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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
SERVIER 427 PCT US

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on 18 MARCH 2010

Signature [signature]

Typed or printed name G. Patrick SAGE

Application Number	Filed
10/502,479	23 July 2004

First Named Inventor
Patrick WUTHRICH

Art Unit	Examiner
1615	Melissa MERCIER, Esq.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 37,710
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

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G. Patrick SAGE
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Telephone number

18 March 2010
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 1 forms are submitted.

* * * * *

Applicants : Patrick WUTHRICH, et al.
Serial No. : 10/502,479
Filed : 23 July 2004
Title : ORODISPERSIBLE PHARMACEUTICAL COMPOSITION OF PERINDOPRIL
Art Unit : 1615
Examiner : Melissa S. MERCIER, Esq.

* * * * *

Mail Stop: AF
Honorable Commissioner for Patents
PO BOX 1450
Alexandria, VA 22313

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

Concurrent with the filing of a Notice of Appeal, and in accordance with the Pre-Appeal Brief Conference Program, the Applicants respectfully request a panel review of the rejections in the Office Action, **a Final Rejection**, mailed on 20 November 2009. No amendments are being filed with this request.

Status of Claims

Claims 11-23 are pending in the application. Claims 11-23 stand rejected. The Final Rejection states that the claims remain rejected for the prior art and double patenting reasons of record, as well as newly applied prior art rejections consistent with the foregoing. Claims 11-15 and 17-23 (presumably a typographical error, likely claims 11-23) are rejected for obviousness under 35 USC § 103(a) based on the disclosure of Luhn (US Patent No. 6,770,368) in view of the Wikipedia product information disclosure of perindopril. Claim 16 is rejected for obviousness under 35 USC § 103 over the disclosure of Luhn (US Patent No. 6,770,368) in view of the Wikipedia product information disclosure of perindopril, and now in view of the disclosure of Dobetti (US Patent No. 6,596,311, published (patented) 22 July 2003). Claims 11-23 are provisionally subject to multiple obviousness-type double patenting rejections in view of copending US Application Serial Nos. 10/502,593 and 10/502,594; and US Patent No. 7,201,922. The obviousness rejections under 35 USC § 103 and the provisional obviousness-type double patent rejections are addressed herein.

Statement of Clear Errors

Rejections under 35 USC § 103(a) based on Luhn, in view of Wikipedia and Dobetti

With respect to the obviousness rejections under 35 USC 103(a), the combined disclosures of Luhn, in view of Wikipedia and Dobetti fail to teach or suggest each and every element recited in rejected Claims 11-23.

The Office reiterates its interpretation of the Luhn disclosure, observing that the patent discloses granules of lactose and starch in Column 2 at line 38, that Example 2 discloses rapidly dissolving tablets ("which dissolve in less than 3 minutes and preferably in less than 1 minute" - quoting the Office) with a hardness within the instant claimed range of 15-50N, as well as tablets comprising magnesium stearate as lubricant, and that the patent also discloses granule production through co-drying at Column 3, line 44.

The Office reiterates its recitation of Wikipedia for the disclosure that perindopril may be used as an ACE inhibitor and, consequently, may be formulated in the tablets as described in Luhn for the treatment of high blood pressure.

Applicants have argued (see Response of 30 June 2009) that, contrary to the Office unsupported allegation, Luhn discloses (at Examples 2 and 3 and Claim 4) granules consisting of lactose and starch with a tableting capacity which results in a tablet hardness greater than 70 N. Luhn also discloses (at column 4) that this tablet hardness distinguishes the disclosed compositions over prior art products. Luhn discloses that the granules possess this tableting capacity while preserving disintegration properties, which disintegration properties Luhn characterizes as being "in the gastric medium" (col. 1, lines 30-32).

Moreover, Applicants have argued that one skilled in the art would recognize that a gastric medium is characterized by a pH less than 2.5 and a volume greater than 25 mL in contrast to an oral medium which is characterized by a pH between 5.5 and 6.5 and a volume less than 1 mL. Therefore, one skilled in the art would also recognize that the disintegration properties of a tablet in a gastric medium may not be extrapolated to an oral medium and that a coventional immediate release tablet which exhibits good disintegration properties in the gastric medium does not necessarily exhibit orodispersible properties, consisting of rapid dispersion in the mouth, before such a tablet has been swallowed.

Finally, the Office has alleged that Luhn discloses a dissolution profile in Example 2 of "less than 3 minutes and preferably less than 1 minute." See the Office Action of 31 December 2008 at page 4, and reiterated with the Final Rejection. This is simply not the case. At best, Luhn discloses disintegration in at least 56 minutes in a gastric medium. See the table in Column 6 and the disclosure in column 1, lines 30-33. It is well settled that to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 180 USPQ 580 (CCPA 1974). With the instant Final Rejection, the Office disavows the eleven (11) disintegration data points reported in Luhn Example 2 and, rather than rely on the allegation of a non-existent 3 minute disintegration data point, concludes that "Luhn does not disclose the disintegration properties of the instant claims." While it is true that Luhn discloses distinguishing disintegration properties, the Office goes on to explain that since Luhn discloses the same lactose/starch granules, tablets made according to the instant invention may be assumed to possess the same functional, i.e., orodispersible, limitation. The Office concludes that the burden is on the applicant to demonstrate actual functional differences between the tablets of Luhn and those of the instant invention.

In the absence of disclosure of disintegration data in Luhn, such may have been the burden of the Applicant. In the instant fact scenario, however, Luhn is actually explicit in its disclosure of disintegration data for a variety of formulations on which the Office has relied. Thus, Luhn does disclose disintegration properties, it is just that these properties distinguish over the instant claims. The Applicant has met its burden, disclosing the disintegration profile of the instant compositions to be less than one (1) minute (see Example 2 at page 6), and the Luhn disclosure of disintegration profiles of its dosage forms at Example 2, as discussed above. What is more, such disintegration data don't compare, thereby demonstrating on the record the required distinction and fulfilling the Applicant's burden. The Office's insistence on further data is misplaced and a clear error.

Finally, the Office issues an additional rejection for obviousness under 35 USC § 103 over the disclosure of Luhn (US Patent No. 6,770,368) in view of the Wikipedia product information disclosure of perindopril, and now in view of the disclosure of Dobetti (US Patent No. 6,596,311, published (patented) 22 July 2003). The bases for rejection are as articulated above with respect to Luhn and Wikipedia, with the additional disclosure of the use of magnesium stearate as lubricant and colloidal silica as glidant drawn from the Dobetti patent. The rejection should fail for the reasons noted with respect to Luhn and Wikipedia, in addition to the fact that Dobetti, published July 2003 isn't prior art to the instant application claiming priority to 23 January 2002.

Provisional Double Patenting Rejection in view of copending US Application Serial Nos. 10/502,593 and 10/502,594; and US Patent No. 7,201,922.

With respect to the provisional double patenting rejections in view of copending US Application Serial Nos. 10/502,593 and 10/502,594; and US Patent No. 7,201,922, the Office has already acknowledged that the respective properties differ from the instant invention for describing distinct active agents.

As summarized in the Supplemental Response of 26 August 2009, in each instance, the Office acknowledges that the solid orodispersible composition disclosed in the cited properties differs from that claimed for describing a distinct active agent. As the different active agents exhibit distinct pharmacological activity, as well as side-effect and interaction profiles, it is submitted that the respective teachings are distinct in their own right and that one of ordinary skill in the art may not be expected to rely with any degree of certainty on such prior teaching in optimizing a formulation as described and claimed in the instant application.

Conclusion

For the reasons enumerated above, as well as the reasons previously presented in the Response and Amendment filed on 30 June 2009, the Applicants respectfully submit that the pending claims are in condition for allowance. The Applicants respectfully request a favorable decision by the committee.

Respectfully submitted,

THE FIRM OF HUESCHEN AND SAGE

G. Patrick SAGE, Attorney #37,710

Dated : 18 March 2010
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Enclosure(s) : Return Postal Card Receipt.

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